Ortho-Clinical Diagnostics
a Johnson-Johnson company
100 Indigo Creek Drive
Rochester, New York 14626-5101

510(k) Summary

JUL 2 1 2006

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k061588

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3143
Contact Person: Michael Byrne

2. **Preparation Date**

June 1, 2006

3. **Device name**

Trade or Proprietary Names:
VITROS Chemistry Products HCY Reagent
VITROS Chemistry Products Calibrator Kit 27
VITROS Chemistry Products HCY Performance Verifiers I, II & III

Common Names:
HCY assay and controls

Classification Names:
Urinary homocystine (nonquantitative) test system (21 CFR 862.1377) Class II
Calibrators (21 CFR 862.1150) Class II
Quality Control material (assayed and unassayed) (21 CFR 862.1660) Class I (general controls). Since these devices (HCY Performance Verifiers I, II & III) are assayed controls, they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

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4. Predicate Devices

The VITROS Chemistry Products HCY assay is substantially equivalent to the previously cleared BIO-RAD® HOMOCYSTEINE by HPLC test (K993107).

The VITROS Chemistry Products HCY Performance Verifiers are substantially equivalent to the previously cleared VITROS Chemistry Products AAT Performance Verifiers (K052819).

5. Device description

The VITROS Chemistry Products HCY Reagent is used in conjunction with the VITROS Chemistry Products Calibrator Kit 27 and VITROS Chemistry Products FS Diluent Pack 2 (BSA/Saline) on VITROS 5,1 FS Chemistry Systems to quantitatively measure total homocysteine (HCY) concentration in human serum and plasma.

The quantitative measurement of homocysteine (HCY) is performed using the VITROS Chemistry Products HCY Reagent in conjunction with the VITROS Chemistry Products Calibrator Kit 27 and on the VITROS 5,1 FS Chemistry Systems. The VITROS Chemistry Products HCY Reagent consists of two dual chambered reagent packs containing three ready-to-use liquid reagents. Disulfide linked homocysteine (oxidized forms) in the sample is reduced by Tris (2-Carboxyethyl) phosphine hydrochloride (TCEP) to form reduced homocysteine. Reduced homocysteine reacts with serine in the presence of cystathionine β-synthase (CBS) to form L-cystathionine. L-cystathionine is broken down by cystathionine β-lyase (CBL) to produce homocysteine, pyruvate and ammonia. Pyruvate is reduced to lactate by lactate dehydrogenase (LDH) using NADH as coenzyme. The concentration of HCY is directly proportional to the amount of NADH converted to NAD^+ and is measured spectrophotometrically at 340 nm. Once a calibration has been performed, the HCY concentration in each unknown sample can be determined using the stored calibration curve and the measured absorbance obtained in the assay of the sample.

The VITROS Chemistry Products Calibrator Kit 27 are prepared from an aqueous solution containing amino acids and inorganic acid. These standards are used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of homocysteine (HCY).

The VITROS Chemistry Products HCY Performance Verifiers I, II and III are prepared from processed human serum to which amino acid and preservative have been added. These are assayed controls used to monitor performance of VITROS HCY Reagents on VITROS 5,1 FS Chemistry Systems.

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The VITROS Chemistry Products FS Diluent Pack 2 (Saline/BSA) is a common reagent that is used by multiple assays on the VITROS 5,1 FS Chemistry System. This is a dual chambered package containing two ready-to-use liquid diluents. Diluent 1 is prepared from processed water to which inorganic salt has been added. Diluent 2 is prepared from processed water to which bovine serum albumin, inorganic salts and preservatives have been added.

The VITROS 5,1 FS Chemistry System is a clinical chemistry instrument that provides automated use of the VITROS Chemistry Products MicroTip® and MicroSlides® range of products. The VITROS 5,1 FS System was cleared for market by 510(k) premarket notification (K031924).

6. Device intended uses

VITROS Chemistry Products HCY Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products HCY Reagent is used to quantitatively measure total homocysteine (HCY) concentration in human serum and plasma. Serum and plasma homocysteine levels can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

VITROS Chemistry Products Calibrator Kit 27: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 27 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of homocysteine (HCY).

VITROS Chemistry Products HCY Performance Verifiers I, II & III: For *in vitro* diagnostic use only. VITROS Chemistry Products HCY Performance Verifiers are assayed controls used to monitor performance of VITROS HCY Reagents on VITROS 5,1 FS Chemistry Systems.

7. Comparison to predicate devices:

The VITROS Chemistry Products HCY Reagent and VITROS Chemistry Products Calibrator Kit 27 are substantially equivalent to the BIO-RAD HOMOCYSTEINE by HPLC test (K993107) (predicate device), which was cleared by the FDA for IVD use.

A least squares linear regression analysis demonstrated the following relationship: $y = 0.98\ x + 1.0$ µmol/L, with a correlation coefficient = 0.97 where y = results obtained using the VITROS Chemistry Products HCY assay and x = results obtained with the commercially available system BIO-RAD HOMOCYSTEINE by HPLC test in conventional/SI units (µmol/L).

The VITROS Chemistry Products HCY Performance Verifiers I, II & III are substantially equivalent to the VITROS Chemistry Products AAT Performance Verifiers I, II & III (K052819) (predicate device) which was cleared by the FDA for IVD use.

In addition to correlation studies, bench testing was performed to determine assay precision, linearity, specificity, expected values, limit of detection, dilution and specimen matrix of the VITROS HCY assay.

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Table 1 Similarities and differences of the assays performed using the VITROS HCY assay and the BIO-RAD HOMOCYSTEINE by HPLC test.

Device Similarities		
Device Characteristic	**VITROS HCY assay (New device) BIO-RAD HOMOCYSTEINE by HPLC test (Predicate device)**	
Intended Use	For *in vitro* diagnostic use. Quantitative determination of total Homocysteine in human plasma or serum.	
Analyte measured	Homocysteine	
Sample Type	Serum and plasma	
Measurement Type	Quantitative	
Device Differences		
Device Characteristic	**VITROS HCY assay (New device)**	**BIO-RAD HOMOCYSTEINE by HPLC test (Predicate device)**
Reportable Range	1.0 –50.0 µmol/L	0.5 – 100 µmol/L
Sensitivity	1.0 µmol/L	0.5 µmol/L
Calibrator levels	Two levels (0, 27 µmol/L)	Single level (15-20 µmol/L)
Calibrator format	Liquid	Lyophilized
Calibrator matrix	Aqueous solution containing amino acids and inorganic acid	Human Serum
Instrumentation	Automated clinical chemistry analyzer	Isocratic HPLC System
Reference Interval	Males: 6.6 – 14.8 µmol/L Females: 4.7 – 12.6 µmol/L	< 15 µmol/L
Method	Homogeneous Enzymatic	Chromatography

Table 2 Similarities and differences of the device characteristics between the VITROS HCY Performance Verifiers I, II & III with the predicate device VITROS AAT Performance Verifiers I, II & III

Device Similarities		
Device Characteristic	**VITROS HCY Performance Verifiers (New Device) VITROS AAT Performance Verifiers (Predicate Device)**	
Indications for Use	For *in vitro* diagnostic use. Assayed controls are used to monitor assay performance on VITROS 5,1 FS Chemistry Systems.	
Matrix	The performance verifiers are prepared from processed human serum with preservatives added.	
Product Type	Assayed Control	
Format	Liquid	
Number of levels	Three	
Differences		
Device Characteristic	**VITROS HCY Performance Verifiers (New Device)**	**VITROS AAT Performance Verifiers (Predicate Device)**
Analytes Reported	Homocysteine (HCY)	α_1-Antitrypsin (AAT)

8. Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products HCY Reagent, VITROS Chemistry Products Calibrator Kit 27 and the VITROS Chemistry Products HCY Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 1 2006

Mr. Michael M. Byrne
Regulatory Associate
Ortho-Clinical Creek Dr.
100 Indigo Creek Dr.
Rochester, NY 14626

Re: k061588
Trade/Device Name: VITROS Chemistry Products HCY Regent
VITROS Chemistry Products Calibrator Kit 27
VITROS Chemistry Products HCY Performance Verifiers I, II, III
Regulation Number: 21 CFR§862.1377
Regulation Name: Urinary homocystine (nonquantitative) test system
Regulatory Class: Class II
Product Code: LPS, JIT, JJX
Dated: June 7, 2006
Received: June 8, 2006

Dear Mr. Byrne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k 061588

Device Name: VITROS Chemistry Products HCY Reagent
VITROS Chemistry Products Calibrator Kit 27
VITROS Chemistry Products HCY Performance Verifiers I, II, and III

Indications for Use: For *in vitro* diagnostic use only. VITROS Chemistry Products HCY Reagent is used to quantitatively measure total homocysteine (HCY) concentration in human serum and plasma. Serum and plasma homocysteine levels can assist in the diagnosis and treatment of patients suspected of having hyperhomocysteinemia and homocystinuria.

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 27 is used to calibrate VITROS 5,1 FS Chemistry Systems for the quantitative measurement of homocysteine (HCY).

For *in vitro* diagnostic use only. VITROS Chemistry Products HCY Performance Verifiers are assayed controls used to monitor performance of VITROS HCY Reagents on VITROS 5,1 FS Chemistry Systems.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
...vision Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K061588